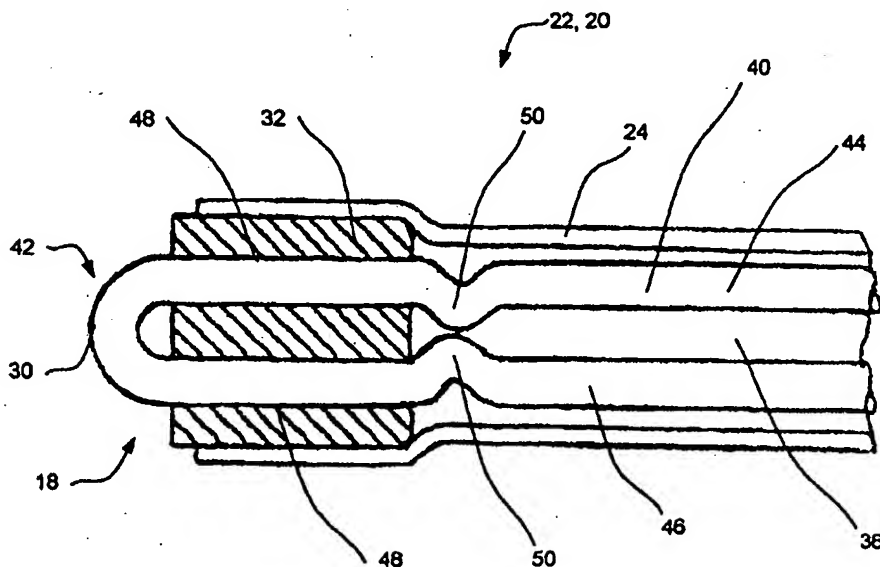




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>7</sup> : <b>A61B 18/14</b>	<b>A1</b>	(11) International Publication Number: <b>WO 00/49956</b> (43) International Publication Date: 31 August 2000 (31.08.00)
(21) International Application Number: PCT/US00/04977 (22) International Filing Date: 24 February 2000 (24.02.00)  (30) Priority Data: 09/256,831          24 February 1999 (24.02.99)          US  (71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One SciMed Place, Maple Grove, MN 55311 (US).  (72) Inventors: DEVORE, Lauri; 17036-13 Avenue Northeast, Seattle, WA 98155 (US). KINSELLA, Bryan; 4500 Harbour Pointe Boulevard #337, Mukilteo, WA 98275 (US).  (74) Agents: SEAGER, Glenn, M. et al.; Crompton, Seager & Tufte, LLC, Suite 895, 331 Second Avenue South, Minneapolis, MN 55401 (US).		(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the</i> <i>claims and to be republished in the event of the receipt of</i> <i>amendments.</i>

(54) Title: PMR CATHETER.



## (57) Abstract

Devices and method for performing percutaneous myocardial revascularization (PMR). A catheter in accordance with the invention includes an elongate shaft having a proximal end and a distal end. The elongate shaft defines a lumen, and a conductor is disposed inside the lumen. An electrode portion is formed by the bent portion of the conductor which extends from the distal end of the elongate shaft. A method in accordance with the present invention may be used to form a wound through the endocardium and into the myocardium of a patient's heart. Collateral damage to the myocardium may be created by infusing pressurized fluid into the wound. A number of fluids may be delivered to a location proximate the wound via the catheter.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## PMR CATHETER

### Related Application

The present application is related to U.S. Patent Application Serial  
5 No. \_\_\_\_\_, filed by the same assignee on even date herewith and  
entitled "Device and Method for Percutaneous Myocardial Revascularization."

### Field of the Invention

The present invention relates generally to devices and methods for  
10 promoting blood circulation to the heart muscle. More particularly, the present  
invention relates to devices and methods for forming holes or channels in the  
walls of a heart chamber such as those created during a percutaneous myocardial  
revascularization (PMR) procedure.

### Background of the Invention

15 Assuring that the heart muscle is adequately supplied with oxygen is  
critical to sustaining the life of a patient. To receive an adequate supply of  
oxygen, the heart muscle must be well perfused with blood. In a healthy heart,  
blood perfusion is accomplished with a system of blood vessels and capillaries.  
20 However, it is common for the blood vessels to become occluded (blocked) or  
stenotic (narrowed). A stenosis may be formed by an atheroma which is typically  
a harder, calcified substance which forms on the walls of a blood vessel.

Historically, individual stenotic lesions have been treated with a number  
of medical procedures including coronary bypass surgery, angioplasty, and

atherectomy. Coronary bypass surgery typically involves utilizing vascular tissue from another part of the patient's body to construct a shunt around the obstructed vessel. Angioplasty techniques such as percutaneous transluminal angioplasty (PTA) and percutaneous transluminal coronary angioplasty (PTCA) are relatively  
5 non-invasive methods of treating a stenotic lesion. These angioplasty techniques typically involve the use of a guidewire and a balloon catheter. In these procedures, a balloon catheter is advanced over a guidewire such that the balloon is positioned proximate a restriction in a diseased vessel. The balloon is then inflated and the restriction in the vessel is opened. A third technique which may  
10 be used to treat a stenotic lesion is atherectomy. During an atherectomy procedure, the stenotic lesion is mechanically cut or abraded away from the blood vessel wall.

Coronary bypass, angioplasty, and atherectomy procedures have all been found effective in treating individual stenotic lesions in relatively large blood  
15 vessels. However, the heart muscle is perfused with blood through a network of small vessels and capillaries. In some cases, a large number of stenotic lesions may occur in a large number of locations throughout this network of small blood vessels and capillaries. The torturous path and small diameter of these blood vessels limit access to the stenotic lesions. The sheer number and small size of  
20 these stenotic lesions make techniques such as cardiovascular bypass surgery, angioplasty, and atherectomy impractical

When techniques which treat individual lesions are not practical a technique known as percutaneous myocardial revascularization (PMR) may be

used to improve the oxygenation of the myocardial tissue. A PMR procedure generally involves the creation of holes, craters or channels directly into the myocardium of the heart. PMR was inspired in part by observations that reptilian heart muscles are supplied with oxygen primarily by blood perfusing directly from within heart chambers to the heart muscle. This contrasts with the human heart, which is supplied by coronary vessels receiving blood from the aorta. Positive clinical results have been demonstrated in human patients receiving PMR treatments. These results are believed to be caused in part by blood flowing within a heart chamber through channels in myocardial tissue formed by PMR.

Increased blood flow to the myocardium is also believed to be caused in part by the healing response to wound formation. Specifically, the formation of new blood vessels is believed to occur in response to the newly created wound. This response is sometimes referred to as angiogenesis. In addition to promoting increased blood flow, it is also believed that PMR improves a patient's condition through denervation. Denervation is the elimination of nerves endings. Specifically, the creation of wounds during a PMR procedure results in the elimination of nerve endings which were previously sending pain signals to the brain as a result of hibernating tissue.

20

#### Summary of the Invention

The present invention pertains to devices and methods for performing percutaneous myocardial revascularization (PMR). A device in accordance with the present invention may be used to form wounds in the myocardium of a

patient's heart. Several general types of wounds may be created with this device. For example, this device may be used to form a channel wound (e.g., a wound with a depth greater than its width). By way of a second example, this device may be used to form a crater wound (e.g., a wound with a width greater than its  
5 depth).

In a preferred embodiment, a catheter in accordance with the present invention includes an elongate shaft having a proximal end and a distal end. The elongate shaft defines a lumen which extends substantially through the elongate shaft. An insulator is fixably attached to the elongate shaft at its distal end. The  
10 insulator includes at least two holes. The catheter also includes a conductor having a bent portion, a first leg portion and a second leg portion. The first and second leg portions of the conductor pass through the holes of the insulator and are disposed in the lumen of the catheter. The bent portion of the conductor substantially forms an electrode protruding from the distal end of the catheter.

15 The distance which the electrode protrudes from the insulator is carefully controlled during the manufacture of the catheter. This helps to control the depth of the wounds which will be created with the catheter during a PMR procedure. In a presently preferred embodiment of the present invention, the electrode proceeds to penetrate the heart until the insulator contacts the heart tissue.

20 The insulator includes two landing zones which extend away from the electrode. The width of the landing zones is generally larger than the width of the electrode. The relatively large area of the landing zones assures that the travel of

the electrode into the heart will stop when the landing zones contact the heart tissue.

It is a desirable feature of this invention that the landing zones extend beyond the wound created in the heart tissue during a PMR procedure. This is  
5 because the wounded tissue is substantially softened, and it is possible for a PMR catheter to be pushed through soft, injured tissue.

The distance which the electrode protrudes from the landing zone and the relative surface areas of these elements are carefully selected to create a therapeutically effective wound while reducing the likelihood of unintentionally  
10 perforating the myocardium. Preferably, a therapeutically effective wound will, at a minimum, perforate through the endocardium and damage blood vessels and capillaries in the myocardium. The likelihood of unintentionally perforating through the myocardium to the epicardium is reduced when the depth of the wound created is only enough to penetrate the endocardium adjacent the  
15 myocardium.

In one embodiment of a device in accordance with the present invention, the conductor defines a conductor lumen and at least one hole in fluid communication with the conductor lumen. The conductor lumen may be used during a PMR procedure to deliver fluid to the distal end of the catheter. The  
20 fluid delivered during the PMR procedure may include contrast, saline, therapeutic agents, etc. The fluid may be used for a number of tasks, including mapping a heart, marking an injury site or promoting angiogenic effects.

In a presently preferred method in accordance with the present invention, pressurized fluid may be delivered to the wound site during or after wound formation. The formation of the wound may be enhanced by collateral damage to the myocardium induced by directing this pressurized fluid into the wound site.

5 The impact of pressurized fluid causes vessels, capillaries and sinuses to rupture. By creating this collateral damage, the number of wounds which need be made during a PMR procedure may be substantially reduced. A second benefit of this collateral damage is that the depth of the wounds required to achieve a therapeutic effect may be reduced. In addition, the injection of contrast creates a fluoroscopic

10 marker of the treatment location.

#### Brief Description of the Drawings

Figure 1 is a plan view of the distal end of a catheter in accordance with the present invention;

15 Figure 2 is a plan view of the distal portion of a catheter in accordance with the present invention with the catheter shown in partial cross section;

Figure 3 is a plan view of a distal portion 22 of a catheter 20 in accordance with a bi-polar embodiment of the present invention;

Figure 4 is a plan view of a distal portion 22 of a catheter 20 in accordance with a further bi-polar embodiment of the present invention;

20

Figure 5 is a plan view of a distal portion 22 of a catheter 20 in accordance with an additional bi-polar embodiment of the present invention;



Figure 6 is a plan view of the distal end of a catheter in accordance with the present invention;

Figure 7 is a plan view of the distal end of a catheter in accordance with the present invention;

5        Figure 8 is a plan view of a distal portion of a catheter in accordance with the present invention with the catheter being shown in partial cross section;

Figure 9 is a plan view of the distal portion of a catheter in accordance with the present invention with the catheter being shown in partial cross section;

10       Figure 10 is a plan view of the distal portion of a catheter in accordance with the present invention with the catheter shown in partial cross section;

Figure 11 is a plan view of the distal end of a catheter in accordance with the present invention with the catheter being shown in partial cross section;

Figure 12 is a plan view of the distal portion of a catheter in accordance with the present invention with the catheter being shown in partial cross section;

15       Figure 13 is a plan view of the distal portion of a catheter in accordance with the present invention with the catheter being shown in partial cross section;

Figure 14 is a plan view of the distal portion of a catheter in accordance with the present invention;

20       Figure 15 is a perspective view of the distal end of the catheter including an alternate electrode assembly;

Figure 16 is a perspective view of the distal end of a catheter including a further alternate embodiment of an electrode assembly;

Figure 17 is a perspective view of the distal end of a catheter including another embodiment of an electrode assembly;

Figure 18 is a perspective view of the distal end of the catheter including a further alternate embodiment of an electrode assembly;

5        Figure 19 is a perspective view of the distal end of a catheter including a further alternate embodiment of an electrode assembly;

Figure 20 is a perspective view of a distal end of a catheter including an alternate embodiment of an electrode assembly;

Figure 21 is a perspective view of the distal end of a catheter including a  
10       further alternate embodiment of an electrode assembly; and

Figure 22 is a perspective view of the distal end of a catheter including a further alternate embodiment of an electrode assembly.

#### Detailed Description of the Invention

15        The following detailed description should be read with reference to the drawings, in which like elements in different drawings are numbered identically. The drawings which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention.

Examples of constructions, materials, dimensions, and manufacturing  
20       processes are provided for selected elements. All other elements employ that which is known to those of skill in the field of the invention. Those skilled in the art will recognize that many of the examples provided have suitable alternatives which may be utilized.

Figures 1 and 2 are plan views of a catheter 20 in accordance with the present invention. Figure 1 is a plan view of a distal end 18 of catheter 20. Catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown) and a distal portion 22. An electrode portion 30 and an insulator 32 are disposed proximate distal end 18 of catheter 20. Insulator 32 includes a plurality of insulator lumens 34.

In Figure 2 a distal portion of catheter 20 is shown in partial cross-section. In Figure 2, it can be appreciated that elongate shaft 24 includes a shaft lumen 36. Catheter 20 includes a conductor 40 having a bent portion 42, a first leg 44, and a second leg 46. First leg 44 and second leg 46 are disposed in lumen 36 of elongate shaft 24. As is best shown in Figure 2, electrode 30 of catheter 20 is generally formed from bent portion 42 of conductor 40. As also shown in Figure 2, insulator 32 defines two holes 48 which are adapted to allow legs 44, 46 of conductor 40 to pass through insulator 32. In a presently preferred embodiment, conductor 40 is adapted to be connected to a radio frequency generator.

One or more retaining elements 50 are formed on conductor 40 proximate insulator 32. In the embodiment of Figure 2, retaining elements 50 have been created by forming two kinks in conductor 40. It will be understood that other embodiments of retaining elements 50 are possible without deviating from the spirit or scope of the present invention. It will also be understood that although two retaining elements are shown in Figure 2, additional embodiments have been envisioned which utilize a single retaining element 50.

As best seen in Figure 2, electrode 30 protrudes beyond insulator 32 of catheter 20. The distance which electrode 30 protrudes is determined in part by the shape of bent region 42 of conductor 40. The distance which electrode 30 protrudes is carefully controlled during the manufacture of catheter 20. This helps to control the depth of the wounds which are created by catheter 20 during a PMR procedure. During such a procedure electrode 30 will proceed to penetrate the heart until insulator 32 contacts the heart tissue. As best seen in Figure 1, insulator 32 includes two landing zones 60 which extend away from electrode 30. In the embodiment of Figure 1, the width of landing zones 60 is substantially greater than the width of electrode 30. The relatively large area of landing zones 60 assures that the travel of electrode 30 into the heart will stop when landing zones 60 contact the heart tissue. It is a desirable feature of this invention that landing zones 60 extend beyond the wound created in the heart tissue during a PMR procedure. This is because the wounded tissue is substantially softened, and it is possible for a PMR catheter to be pushed through soft, injured tissue.

The distance which electrode 30 protrudes from landing zones 60 and the relative surface areas of these elements are carefully selected to create a therapeutically effective wound while reducing the likelihood of unintentionally perforating the myocardium. A therapeutically effective wound generally must perforate the endocardium and damage blood vessels and capillaries in the myocardium. The likelihood of unintentionally perforating the myocardium is reduced when the depth of wound created is only enough to penetrate the endocardium.

By way of example, the dimensions below have been found effective in creating therapeutically effective wounds while reducing the likelihood that the myocardium will be punctured through to the epicardium.

In a presently preferred embodiment the distance electrode 30 protrudes from landing zones 60 is between about 0.005 and about 0.4 inches. In a presently most preferred embodiment the distance electrode 30 protrudes from landing zones 60 is between about 0.010 and about 0.035 inches.

In a presently preferred embodiment, in accordance with Figure 2, the diameter of conductor 40 in bent portion 42 is between 0.003 and about 0.030 inches. In a presently most preferred embodiment, in accordance with Figure 2, the diameter of conductor 40 in bent portion 42 is between about 0.008 and about 0.012 inches. It should be understood that the diameter of conductor 40 may vary along its length, and conductor 40 may include one or more tapered sections to optimize shaft support and flexibility. In a presently preferred embodiment, conductor 40 is about 70 inches long having a distal portion with a diameter of about 0.010 inches and a proximal portion with a diameter of about 0.022 inches. In this presently preferred embodiment, conductor 40 includes a transition portion which is about 8 inches long and which tapers from the diameter of the proximal portion to the diameter of the distal portion.

In a presently preferred embodiment in accordance with Figure 2, the bend radius of electrode 30 is between about 0.004 and about 0.1 inches. In the presently most preferred embodiment in accordance with Figure 2, the bend radius of electrode 30 is between about 0.012 and about 0.023 inches.

In a presently preferred embodiment the width of landing zones 60 extending from two sides of electrode 30 is between about 0.007 and about 0.050 inches. In a presently most preferred embodiment the width of landing zones 60 extending from two sides of electrode 30 is between about 0.015 and about 0.030 inches. As described above, and shown in Figure 1, there are two landing zones 60 extending away from electrode 30 in the embodiment of Figures 1 and 2.

Although breaking through the endocardium may be sufficient treatment for many patients, for some patients the physician may prefer to penetrate the myocardium with electrode 30 a certain distance. As described previously, the depth which electrode 30 penetrates heart tissue may be controlled by the geometry of electrode 30 and landing zones 60. The distance which electrode 30 protrudes from landing zones 60 is carefully controlled during the manufacture of catheter 20. A number of models of catheter 20 may be supplied to a physician, each model being adapted to produce wounds of a specific depth. The depth of the wound created is influenced by the depth which the electrode penetrates the heart tissue. Other factors may influence the depth of wound created without deviating from the spirit or scope of the present invention. For example, the depth of wound created may be effected by the magnitude and frequency of the radiofrequency energy applied to electrode 30. By way of a second example, the depth of wound produced may be effected by the length of time the electrode is energized.

Conductor 40 and electrode portion 30 may be comprised of stainless steel, Nitinol, or a number of other materials which are conductive and

biocompatible. In a presently preferred embodiment, conductor 40 and electrode portion 30 are comprised of Nitinol. Embodiments of electrode 30 have also been envisioned wherein electrode 30 includes a radiopaque material. Examples of radiopaque material which may be included in electrode 30 include: gold, platinum, silver, and tungsten.

Insulator 32 may be formed from ceramic, glass, glass-ceramic, polytetrafluoroethylene (PTFE), polyimide, or a number of other materials which are non-conductive and biocompatible and/or thermally insulated and biocompatible. In a presently preferred embodiment, insulator 32 is formed from ceramic. Further embodiments of insulator 32 have been envisioned which include a radiopaque material. The radiopaque materials which may be suitable for inclusion in an insulator 32 in some embodiments, include: gold, platinum, silver, tungsten, barium sulfide and bismuth oxide. In a presently preferred radiopaque embodiment of insulator 32, a radiopaque material is selectively applied to the outer diameter of insulator 32. A presently preferred radiopaque material is a platinum/iridium blend.

Although conductor 40 in the embodiment of Figures 1 and 2 is circular in cross section, it should be understood that other cross-sectional shapes are possible without deviating from the spirit or scope of the invention. For example, the cross-sectional shape of conductor 40 could be rectangular, square, triangular, oval, etc.

In a presently preferred embodiment, elongate shaft 24 is comprised of polyether block amide (PEBA). Polyether block amide is commercially available

from Atomchel Polymers of Birsdsboro Pennsylvania under the trade name PEBAX. Elongate shaft 24 may be comprised of other materials without departing from the spirit of scope of this invention. Examples of materials which may be suitable in some applications include: polyethylene (PE), polypropylene  
5 (PP), polyvinylchloride (PVC), polyurethane, polyimide, and polytetrafluoroethylene (PTFE).

As described above, in a presently preferred embodiment, insulator 32 and elongate shaft 24 are separate elements comprised of ceramic and PEBA respectively. However, it should be understood that these two elements could be  
10 combined into one element formed of one material without deviating from the spirit or scope of the present invention. In the embodiment of Figures 1 and 2, elongate shaft 24 has a single lumen 36. It will be understood that embodiments of the present invention have been envisioned in which shaft 26 has multiple lumens 36.

15 During a PMR procedure, catheter 20 is preferably advanced through the vasculature of a patient until distal end 18 is proximate the endocardium of a patient's heart. The route taken by catheter 20 will normally be by way of the femoral artery and the aorta to the left ventricle.

Those of skill in the art will appreciate that other routes may be taken  
20 without deviating from the spirit or scope of the present invention. For example, catheter 20 may enter the right ventricle by way of the pulmonary vein or femoral vein. As a second example of an alternate route which may be taken by catheter 20, catheter 20 may enter the right ventricle from the left ventricle by passing



through the septal wall. As a third example of an alternate route which may be taken by catheter 20, catheter 20 may enter the body at the carotid artery and reach the heart therethrough.

To facilitate the advancement of catheter 20 through the vasculature of the patient, catheter 20 may include a slippery material disposed on the outer surfaces of elongate shaft 24. Once inside the heart, distal end 18 of catheter 20 is positioned proximate the endocardium, preferably, such that electrode portion 30 is in contact with the endocardium. Electrode portion 30 may then be energized to form a wound.

Typically, an additional step in a method in accordance with the present invention is to identify areas of tissue within the patient's heart which are candidates for PMR. To facilitate ease of discussion, areas of tissue in the heart muscle may be generally classified healthy or hibernating. Healthy tissue is tissue which is well perfused with blood, and subsequently well supplied with oxygen. Hibernating tissue is tissue which is not currently contracting to assist in the pumping of blood. However, if hibernating tissue is adequately supplied with blood, it will once again begin contracting and contribute to the pumping of blood.

A number of methods may be used to identify hibernating tissue. For example, contrast media may be injected into the coronary vessels to identify regions of the heart into which the contrast medium does not flow due to obstruction of the vessels into which the media was injected. In this case, the

hibernating region will be identified by the lack of flow or abnormally low flow distally of the obstruction in the coronary vessel or vessels.

A second method which may be used to identify hibernating regions of the heart involves injecting contrast media directly into the heart chambers.

5 Hibernating tissue may then be identified by locating areas of generally poor wall motion of the heart chambers. When this method is selected, the contrast media may be delivered to the heart chambers via catheter 20. Shaft lumen 36 and insulator lumens 34 of catheter 20 provide a suitable channel for delivering contrast media from a location outside the patient's body to distal end 18 of  
10 catheter 20.

Once hibernating regions within the heart are identified, these regions may be targeted for PMR. Electrode 30 will be positioned proximate the targeted heart tissue. In a presently preferred method, a contact detecting means in conjunction with electrode 30 will be used to sense contact between electrode 30 and heart  
15 tissue. This method is further detailed in a co-pending U.S. Patent Application Serial No. \_\_\_\_\_, filed by the same assignee on even date herewith and entitled "Device and Method for Percutaneous Myocardial Revascularization."

During a PMR procedure, electrode 30 will proceed to penetrate the heart  
20 until landing zones 60 of insulator 32 contact the heart tissue. As described above, landing zones 60 have a relatively large surface area to assure that the depth of electrode penetration will be controlled. The depth of the wound is also influenced by the distance which electrode 30 protrudes from landing zones 60.

As described above, this distance is carefully controlled during the manufacture of catheter 20.

As described above, the distance which electrode 30 protrudes from landing zones 60 and the relative surface areas of these elements are carefully selected to create a therapeutically effective wound while reducing the likelihood of unintentionally perforating the myocardium. Preferably, a therapeutically effective wound will perforate through the endocardium and damage blood vessels and capillaries in the myocardium. The likelihood of unintentionally perforating the myocardium to the epicardium is reduced when the depth of wound created is only enough to penetrate the endocardium.

Although breaking through the endocardium may be sufficient treatment for many patients, for some patients a physician may desire to penetrate the myocardium with electrode 30 a certain distance. As described previously, the depth which electrode 30 penetrates the heart tissue, may be controlled by the geometry of electrode 30 and landing zones 60. A number of models of catheter 20 may be provided to a physician, each model being adapted to create wounds of a particular depth. The depth of wound created is influenced by the depth which electrode 30 penetrates heart tissue. Other factors may influence wound depth without deviating from the spirit and scope of the present invention. For example, the magnitude and frequency of the radiofrequency energy applied to electrode 30 may effect the depth of wound created during a PMR procedure. By way of a second example, the length of time electrode 30 is energized may effect the depth of wound created.

In a presently preferred method, a fluid under pressure is forced into the wound by way of shaft lumen 36 and insulator lumens 34. This fluid may include saline, radiopaque contrast media, a therapeutic agent, a caustic agent, or any combination of these.

- 5       The formation of the wound may be enhanced by collateral damage to the myocardium induced by directing this pressurized fluid into the wound site. The impact of the pressurized fluid causes vessels, capillaries, and sinuses to rupture. By creating this collateral damage, the number of wounds which must be made during a PMR procedure can be substantially reduced. Injecting a fluid including
- 10   a radiopaque contrast media into the wound serves to create a radiopaque marker of the treatment site. Injecting a fluid, including a therapeutic agent, serves to promote angiogenesis.

- Forcing fluid under pressure into the wound may be used to create collateral damage. Collateral damage is created when vessels, capillaries, and
- 15   sinuses within the myocardium are ruptured. Thus collateral damage will increase the healing response of the body. The fluid under pressure may be forced into the wound while electrode 30 is energized or during a time when electrode 30 is not energized. In either case, the distal end of catheter 20 is positioned proximate the wound. Because electrode 30 was used to create the wound, catheter 20 is in an
- 20   ideal position to inject fluid into the wound. If a separate catheter was used to deliver fluid, the distal end of that catheter would need to be positioned over the wound.

A PMR system for use with catheter 20 may include a means for controlling the flow of fluid through catheter 20. In one embodiment of the invention, the means for controlling would direct fluid to be injected into the wound immediately after each spark. In a second envisioned embodiment of the present invention, a PMR system for use with catheter 20 would include a foot pedal capable of activating the means for controlling fluid flow, and the means for energizing electrode 30. In this embodiment of the present invention, fluid would flow from the distal end of catheter 20 while electrode 30 was energized. Several other embodiments of the means for controlling fluid flow are possible without deviating from the spirit or scope of the present invention. For example, fluid may be delivered a set time after energy is delivered.

A second benefit of collateral damage is that it may reduce the wound depth needed to create clinically effective results. The depth of the wound may be limited so that the wound just passes through the endocardium. Once the endocardium is perforated, pressure from infused fluid may be used to rupture myocardial vessels, capillaries and sinuses without further ablation or removal of tissue. As discussed previously, limiting the depth of ablation reduces the likelihood of unintentional myocardial perforation.

Those with skill in the art will appreciate that catheter 20 may also be used in procedures where collateral damage is deemed undesirable. Collateral damage may be avoided by not delivering fluid through catheter 20, or by delivering fluid through catheter 20 at a relatively low pressure. In addition to promoting increased blood flow, it is also believed that PMR improves a patient's condition

through denervation. Specifically, the PMR induced wounds result in elimination of nerve endings which were previously sending pain signals to the brain as a result of hibernating tissue.

As described previously, increased blood flow to the myocardium is caused in part by the healing response to wound formation during PMR. Specifically, the formation of new vessels or capillaries is believed to occur in response to a newly created wound. The revascularization of myocardial tissue may be promoted by delivering a therapeutic agent to the wound area. Examples, of therapeutic agents include growth factors, drugs and caustic agents. In one embodiment of the present invention, the PMR procedure includes the step of delivering a therapeutic agent to the wound site via catheter 20. Shaft lumen 36 and insulator lumens 34 of catheter 20 provide a suitable channel for delivering a therapeutic agent to the wound site from a location outside the patient's body.

Fluids delivered via catheter 20 during a PMR procedure may provide additional benefits. For example, fluid delivered via catheter 20 may serve to cool electrode 30 during a PMR procedure. As a second example, fluid delivered via catheter 20 may serve to remove debris from the wound. It should be understood that steps may be omitted from the method described above, or the order of the steps may be changed without deviating from the spirit or scope of the present invention.

Those with skill in the art will recognize that catheter 20 may be used with bi-polar or mono-polar PMR techniques. In a mono-polar PMR procedure, a

return or neutral electrode is generally attached to the exterior of the patient. In a bi-polar PMR technique, a return or neutral electrode is positioned in close proximity to distal end 18 of catheter 20. For example, a tubular return electrode may be disposed on the outer surface of catheter 20 proximate its distal end 18.

5           A bi-polar embodiment of the present invention is illustrated in Figure 3. Figure 3 is a plan view of a distal portion 22 of a catheter 20. As in the embodiment of Figures 1 and 2, catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. An electrode portion 30 and a return electrode 332 are disposed proximate a distal end 18 of catheter 20.

10           As shown in Figure 3, elongate shaft 24 includes a lumen 36. Catheter 20 includes a conductor 40 having a bent portion 42, a first leg 44, and a second leg 46. First leg 44 and second leg 46 are disposed in lumen 36. Electrode 30 of catheter 20 is generally formed from bent portion 42 of conductor 40. Return electrode 332 defines two holes 48. Two sleeves 302 are disposed inside holes  
15 48. First leg 44 and second leg 46 pass through sleeves 302. In the embodiment of Figure 3, return electrode 332 is comprised of a conductive material allowing it to serve as a return electrode in a bi-polar PMR configuration. Sleeves 302 are comprised of a non-conductive material, and serve to insulate conductor 40 from return electrode 332. A return conductor 304 is coupled to return electrode 332.  
20 Return conductor 332 is suitably insulated so that it will not make electrical contact with conductor 40. In one envisioned embodiment of the present invention, return conductor 332 is disposed in a separate lumen of elongate shaft 24.

Figure 4 is a plan view of a distal portion 22 of a catheter 20 in accordance with a bi-polar embodiment of the present invention. As in the embodiment of Figures 1 and 2, catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. An electrode portion 30 and an insulator 32 are  
5 disposed proximate a distal end 18 of catheter 20.

As shown in Figure 4, elongate shaft 24 includes a lumen 36. Catheter 20 includes a conductor 40 having a bent portion 42, a first leg 44, and a second leg 46. First leg 44 and second leg 46 are disposed in lumen 36. Electrode 30 of catheter 20 is generally formed from bent portion 42 of conductor 40. Insulator  
10 32 defines two holes 48 which are adapted to allow legs 44, 46 of conductor 40 to pass through insulator 32.

In the embodiment of Figure 4, a return electrode 332 is disposed about the outer surface of insulator 32. Return electrode 332 is comprised of a conductive material allowing it to serve as a return electrode in a bi-polar PMR  
15 configuration. A return conductor 304 is coupled to return electrode 332. Return conductor 332 is suitably insulated so that it will not make electrical contact with conductor 40. In one envisioned embodiment of the present invention, return conductor 332 is disposed in a separate lumen of elongate shaft 24. As shown in Figure 4, return electrode 332 protrudes beyond the distal end of elongate shaft  
20 24.

Figure 5 is a plan view of a distal portion 22 of a catheter 20 in accordance with a bi-polar embodiment of the present invention. As in the embodiment of Figures 1 and 2, catheter 20 includes an elongate shaft 24, a proximal end 26 (not



shown), and a distal portion 22. An electrode portion 30 and an insulator 32 are disposed proximate a distal end 18 of catheter 20.

In the embodiment of Figure 5, elongate shaft 24 is comprised of an outer tubular member 312 and an inner tubular member 310 having a lumen 36. A  
5 conductive coating 314 is disposed on the outer diameter of inner tubular member 310. Outer tubular member 312 is comprised of a non-conductive material and generally overlays conductive coating 314. In one embodiment outer tubular member 312 is comprised of shrink tubing. In a second embodiment outer tubular member 312 is comprised of a non-conductive coating. A portion of conductive  
10 coating 314 proximate distal end 18 is not covered by outer tubular member 312. Embodiments of the present invention have been envisioned in which exposed portions of conductive coating 314 act as a return electrode. In the embodiment of Figure 5, a return electrode 316 is disposed about and electrically coupled to conductive coating 314. In a presently preferred embodiment, return electrode  
15 316 is comprised of a material which is conductive and radiopaque. Examples of suitable materials include gold, platinum, silver, and tungsten.

In the embodiment of Figure 5, conductive coating 314 acts as an electrical conductor coupling return electrode 316 to the radio frequency generator used in a PMR procedure. Catheter 20 of Figure 5 also includes an  
20 electrode 30 generally formed from bent portion 42 of conductor 40. In one embodiment of the present invention, conductor 40 is electrically coupled to a radio frequency generator (not shown) by a cable (not shown). In a presently preferred embodiment, conductor 40 is directly attached to the cable.

Figure 6 is a plan view of a distal portion 22 of a catheter 20 in accordance with one embodiment of the present invention. As in the embodiment of Figures 1 and 2, catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. An electrode portion 30 and an insulator 32 are  
5 disposed proximate a distal end 18 of catheter 20.

As shown in Figure 6, elongate shaft 24 includes a lumen 36. Catheter 20 includes a conductor 40 having a bent portion 42, a first leg 44, and a second leg 46. First leg 44 and second leg 46 are disposed in lumen 36. Electrode 30 of catheter 20 is generally formed from bent portion 42 of conductor 40. Insulator 32  
10 defines two holes 48 which are adapted to allow legs 44, 46 of conductor 40 to pass through insulator 32. A groove 340 is disposed on the outer diameter of insulator 32. A band 342 is disposed in groove 340. In a presently preferred embodiment, band 342 is comprised of a radiopaque material. When radiographic equipment is used in conjunction with catheter 20, band 342 aids the physician in  
15 locating distal end 18 of catheter 20. Band 342 may be comprised of a number of radiopaque materials including gold, platinum, silver, tungsten, barium sulfate, and bismuth oxide. In a presently preferred embodiment, band 342 is a platinum/iridium blend.

Referring now to Figures 7 and 8, which illustrate an additional  
20 embodiment of catheter 20. Figure 8 is a plan view of distal portion 22 of catheter 20 shown in partial cross section. Figure 7 is a plan view of distal end 18 of the embodiment of catheter 20 shown in Figure 8. As in the previous embodiment, catheter 20 includes an elongate shaft 24, a proximal end 26 (not

shown), a distal portion 22, and a distal end 18. An electrode portion 30 and an insulator 32 are disposed proximate distal end 18 of catheter 20. As best seen in Figure 7, insulator 32 includes two landing zones 60 which extend away from electrode 30.

5. As best shown in Figure 8, elongate catheter 20 includes a conductor 140 having a bent portion 142, a first leg 144, and a second leg 146. Conductor 140 also defines a lumen 200 and two holes 202 which are in fluid communication with lumen 200. Holes 202 in conductor 40 are shown most clearly in Figure 7.

First leg 144 and second leg 146 are disposed in lumen 36 of elongate shaft 24. Electrode 30 is generally formed from bent portion 142 of conductor 140. As best shown in Figure 8, insulator 32 defines two holes 48 which are adapted to allow legs 144, 146 of conductor 140 to pass through insulator 32.

A retaining element 150 is formed on conductor 140 proximate insulator 32. In the embodiment of Figure 8, retaining element 150 has been created by forming a weld bead 204 on conductor 140. Weld bead 204 may be formed using a number of manufacturing processes. For example, welding, solder, and brazing are all suitable processes of creating weld bead 204. It will be understood that other embodiments of retaining element 150 are possible without deviating from the spirit or scope of the present invention. In the embodiment of Figures 3 and 4, weld bead 204 also serves the function of sealing the end of lumen 200.

As in the previous embodiment, electrode 30 protrudes beyond insulator 32 of catheter 20. The distance which electrode 30 protrudes is determined in part by the shape of bent region 142 of conductor 140. The distance which electrode

30 protrudes is carefully controlled during the manufacture of catheter 20. This helps to control the depth of the wounds created by catheter 20 during a PMR procedure. During such a procedure electrode 30 will proceed to penetrate the heart until insulator 32 contacts the heart tissue.

5       As best seen in Figure 7, insulator 32 includes two landing zones 60 which extend away from electrode 30. The width of landing zones 60 is substantially greater than the width of electrode 30 in Figure 7. The relatively large area of landing zones 60 assure that the travel of electrode 30 into the heart tissue will stop when landing zones 60 contact the heart tissue. It is a desirable feature of  
10 this invention that landing zones 60 generally extend beyond the wound created in the heart tissue created during a PMR procedure. This is because the wounded tissue is substantially softened, and it is possible for a PMR catheter to be pushed through soft, injured tissue.

      The distance which electrode 30 protrudes from landing zones 60 and the  
15 relative surface areas of these elements are carefully selected to create a therapeutically effective wound while reducing the likelihood of unintentionally perforating the myocardium. Preferably, a therapeutically effective wound will at a minimum perforate through the endocardium and damage blood vessels and capillaries in the myocardium. The likelihood of unintentionally perforating  
20 through the myocardium to the epicardium is reduced when the depth of wound created is only enough to penetrate the endocardium.

      During a PMR procedure, catheter 20 is preferably advanced through the vasculature of a patient until distal end 18 is proximate the endocardium of the

patient's heart. The route taken by catheter 20 will normally be by way of the femoral artery and the aorta to the left ventricle. Those with skill in the art will appreciate that other routes may be taken by catheter 20 without deviating from the spirit or scope of the present invention. For example, the right ventricle may  
5 be accessed via the pulmonary vein or the femoral vein. By way of a second example, the septal approach may be used. In a septal approach, the distal end of catheter 20 first enters one ventricle (the left or the right). A PMR procedure may be performed in that ventricle. The distal end of catheter 20 may then enter the other ventricle by passing through the septal wall. A third example of a route  
10 which may be taken by catheter 20 is a route via the carotid artery.

To facilitate the advancement of catheter 20 through the vasculature of the patient, catheter 20 may include a slippery material disposed on the outer surfaces of elongate shaft 24. Once inside the heart, distal end 18 of catheter 20 is positioned proximate the endocardium, preferably, such that electrode portion 30  
15 is in contact with the endocardium. Contact between the endocardium and electrode 30 may be detected electronically. A method is further detailed in co-pending U.S. Patent Application Serial No. \_\_\_\_\_, filed by the same assignee on even date herewith and entitled "Device and Method for Percutaneous Myocardial Revascularization.". The disclosure of this co-pending application is  
20 hereby incorporated by reference into the present application.

An additional method which may be used to determine the location of electrode 30 is through radiographic techniques. The use of radiographic techniques may be enhanced by selectively incorporating radiopaque material into

catheter 20. In one embodiment of the present invention, a radiopaque material is disposed about the outer diameter of insulator 32. The radiopaque material may be comprised of a band of metal. Materials which may be suitable for this marker band include: gold, platinum, silver, and tungsten. A radiopaque material may  
5 also be included in electrode 30 and/or insulator 32.

Typically, an additional step in a method in accordance with the present invention is to identify areas of tissue within the patient's heart which are candidates for PMR. To facilitate ease of discussion, areas of tissue in the heart muscle may be generally classified healthy or hibernating. Healthy tissue is tissue  
10 which is well perfused with blood, and subsequently well supplied with oxygen. Hibernating tissue is tissue which is not currently contracting to assist in the pumping of blood. However, if hibernating tissue is adequately supplied with blood, it will once again begin contracting and contribute to the pumping of blood.

15 A number of methods may be used to identify hibernating tissue. For example, contrast media may be injected into the coronary vessels to identify regions of the heart into which the contrast medium does not flow due to obstruction of the vessels into which the media was injected. In this case, the hibernating region will be identified by the lack of flow or abnormally low flow  
20 distally of the obstruction in the coronary vessel or vessels.

A second method which may be used to identify hibernating regions of the heart involves injecting contrast media directly into the heart chambers. Hibernating tissue may then be identified by locating areas of generally poor wall

motion of the heart chambers. When this method is selected, the contrast media may be delivered to the heart chambers via catheter 20. Lumen 200 and holes 202 of conductor 140 provide a channel for delivering contrast media from a location outside the patients body to distal end 18 of catheter 20.

5           Once hibernating regions within the heart area identified, these regions are candidates for PMR. During the PMR procedure, electrode 30 will proceed to penetrate the heart until landing zones 60 of insulator 32 contact the heart tissue. As described above, landing zones 60 have a relatively large surface area to assure that the depth of the wound will be controlled. The depth of the wound is  
10 also controlled by the distance which electrode 30 protrudes from landing zones 60. As described above, this distance is carefully controlled during the manufacture of catheter 20.

As described above, the distance which electrode 30 protrudes from landing zones 60 and the relative surface areas of these elements are carefully  
15 selected to create a therapeutically effective wound while reducing the likelihood of unintentionally perforating the myocardium. Preferably, a therapeutically effective wound generally will, at a minimum, perforate through the endocardium and damage blood vessels and capillaries in the myocardium. The likelihood of unintentionally perforating through the myocardium to the epicardium is reduced  
20 when the depth of wound created is only enough to penetrate the endocardium.

In a presently preferred method, a fluid under pressure is forced into the wound through lumen 200 and holes 202 of conductor 140. This fluid may include saline, contrast media, a therapeutic agent, a caustic agent, or any

combination of these. By forcing fluid under pressure into the wound, vessels, capillaries, and sinuses in the myocardium will be collaterally damaged within an area proximate the wound. This collateral damage will increase the healing response by angiogenesis. The fluid under pressure may be forced into the wound  
5 while electrode 30 is energized, or during a time when electrode 30 is not energized.

The formation of the wound may be enhanced by collateral damage to the myocardium induced by directing this pressurized fluid into the wound site. The impact of the pressurized fluid causes vessels, capillaries, and sinuses to rupture.  
10 By creating this collateral damage, the number of wounds which need to be made during a PMR procedure may be substantially reduced.

A second benefit of collateral damage is that it may reduce the wound depth needed to create clinically effective results. The depth of the wound may be limited so that the wound just passes through the endocardium. Once the  
15 endocardium is perforated, pressure from infused fluid may be used to rupture the myocardial vessels, capillaries and sinuses without further ablation or removal of tissue. Limiting the depth of ablation reduces the likelihood of unintentional myocardial perforation. In addition, the injection of a fluid containing a radiopaque contrast solution creates a fluoroscopic marker of the treatment  
20 location.

An additional benefit of having holes 202 disposed at the distal end of catheter 20 is that they permit the fluid to be injected into the wound immediately



after it is created. This eliminates the need to withdraw catheter 20 and position a second catheter to deliver fluid to the wound.

As described previously, increased blood flow to the myocardium is caused in part by the healing response to wound formation during PMR. Specifically, the formation of new vessels or capillaries is believed to occur in response to a newly created wound. The revascularization of myocardial tissue may be promoted by delivering a therapeutic agent to the wound area. Examples, of therapeutic agents include growth factors and drugs. In one embodiment of the present invention, the PMR procedure includes the step of delivering a therapeutic agent through lumen 200 and holes 202 of conductor 140.

In a presently preferred method, a fluid is delivered via catheter 20 to the patient proximate the wound. This fluid may include saline, radiopaque contrast media, a therapeutic agent, a caustic agent, or any combination of these. Injecting a fluid including a radiopaque contrast media acts to create a radiopaque marker of the treatment site. Injecting a fluid into a wound which includes a therapeutic agent acts to enhance the angiogenesis response of the body. An embodiment of the present invention has been envisioned where the same control means which enables radiofrequency energy to energize electrode 30 may be used to enable fluid to be injected into the wound from the distal end of catheter 20. In a presently preferred embodiment, the control means of the PMR system directs fluid to be injected into the wound immediately after each spark. Fluids delivered via catheter 20 during a PMR procedure may provide additional benefits. For example, fluid delivered via lumen 200 of conductor 140 may serve to cool

electrode 30 during a PMR procedure. As a second example, fluid delivered via catheter 20 may serve to remove debris from the wound. It should be understood that steps may be omitted from the method described above, or the order of the steps may be changed without deviating from the spirit or scope of the present  
5 invention.

Figure 9 is a plan view of a distal portion 22 of a catheter 20 in accordance with an alternate embodiment of the present invention. As in the previous embodiments catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. An electrode portion 30 and an insulator 32 are  
10 disposed proximate a distal end 18 of catheter 20.

As shown in Figure 9, elongate shaft 24 includes two lumens 36A, 36B. Catheter 20 includes a conductor 40 having a bent portion 42, a first leg 44, and a second leg 46. First leg 44 and second leg 46 are disposed in lumens 36A and 36B respectively. Electrode 30 of catheter 20 is generally formed from bent portion  
15 42 of conductor 40. Insulator 32 defines two holes 48 which are adapted to allow legs 44, 46 of conductor 40 to pass through insulator 32. Insulator 32 defines additional holes (not shown) which allow fluid to pass therethrough.

Two retaining elements 50 are located on conductor 40 proximate insulator 32. In the embodiment of Figure 9, each retaining element 50 is a sleeve  
20 surrounding conductor 40. Each retaining element 50 has been fixed to conductor 40 with a crimping process. Retaining elements 50 assist in maintaining the position of bent portion 42; preventing it from moving before, or during a PMR procedure. Insulator 32, acting in conjunction with retaining elements 50,

supports bent portion 42 of conductor 40, preventing it from being deformed during a PMR procedure.

Figure 10 is a plan view of a distal portion 22 of a catheter 20 in accordance with an alternate embodiment of the present invention. As in the previous embodiments catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. An electrode portion 30 and an insulator 32 are disposed proximate a distal end 18 of catheter 20.

Elongate shaft 24 includes two lumens 36A, 36B. Catheter 20 includes a conductor 640 having a bent portion 642, a first portion 652, and a second portion 654. As shown in Figure 10, the outer diameter of second portion 654 is smaller than the outer diameter of first portion 652. Conductor 640 includes a step proximate the intersection between first portion 652 and second portion 654.

First portion 652 of conductor 640 is substantially disposed in lumen 36A of elongate shaft 24. Second portion 654 of conductor 640 passes through insulator 32 via two holes 48. The remaining portion of second portion 654 is disposed in lumen 36B of elongate shaft 24. A bent portion 642 of conductor 640 extends beyond insulator 32; an electrode 30 is generally formed by bent portion 642.

A retaining element 50 is located on second portion 654 proximate insulator 32. In the embodiment of Figure 10, retaining element 50 is a sleeve surrounding conductor 640. A number of processes may be used to fix retaining element 50 onto conductor 640. For example, there may be an interference fit between the sleeve and conductor 640. Other examples of acceptable retention

methods include soldering, brazing, welding, crimping, and adhering with an adhesive. Retaining element 50 and step 650 assist in maintaining the position of bent portion 642; preventing it from moving before, or during a PMR procedure. Insulator 32, acting in conjunction with retaining element 50, supports bent  
5 portion 642 of conductor 640, preventing it from being deformed during a PMR procedure.

Figure 11 is a plan view of a distal portion 22 of a catheter 20 in accordance with an alternate embodiment of the present invention. As in the previous embodiments catheter 20 includes an elongate shaft 24, a proximal end  
10 26 (not shown), and a distal portion 22. An electrode portion 30 and an insulator 32 are disposed proximate a distal end 18 of catheter 20.

As shown in Figure 11, elongate shaft 24 includes a lumen 36. Catheter 20 includes a conductor 740 having a bent portion 742, a first leg 744, and a second leg 746. First leg 744 and second leg 746 are substantially disposed in  
15 lumen 36. Electrode 30 of catheter 20 is generally formed by bent portion 742 of conductor 740. Insulator 32 defines two holes 48 which are adapted to allow legs 744, 746 of conductor 740 to pass through insulator 32.

A bond 750 is formed between first leg 744 and second leg 746 of conductor 740. A number of processes may be used to create bond 750. For  
20 example, bond 750 may be created by applying an adhesive between first leg 744 and second leg 746. Other techniques which may be used to fabricate bond 750 include welding, brazing, and soldering.

Figure 12 is a plan view of a distal portion 22 of a catheter 20 in accordance with an alternate embodiment of the present invention. As in the previous embodiments catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. An electrode portion 30 and an insulator 32 are disposed proximate a distal end 18 of catheter 20.

As shown in Figure 12, elongate shaft 24 includes two lumens 36A, 36B. Catheter 20 includes a conductor 40 having a bent portion 42, a first leg 44, and a second leg 46. First leg 44 and second leg 46 are substantially disposed in lumens 36A and 36B respectively. Electrode 30 of catheter 20 is generally formed from bent portion 42 of conductor 40. Insulator 32 defines two holes 48 which are adapted to allow legs 44, 46 of conductor 40 to pass through insulator 32.

Two retaining elements 50 are located on conductor 40 proximate insulator 32. In the embodiment of Figure 12, each retaining element 50 is formed from material of conductor 40 which has been displaced to create a localized area with a greater width. A crimping or staking process may be used to create deformations of this type in conductor 40.

Retaining elements 50 assist in maintaining the position of bent portion 42; preventing it from moving before, or during a PMR procedure. Insulator 32 acting in conjunction with retaining elements 50 supports bent portion 42 of conductor 40, preventing it from being deformed during a PMR procedure.

Figure 13 is a plan view of a distal portion 22 of a catheter 20 in accordance with an alternate embodiment of the present invention. As in the previous embodiments catheter 20 includes an elongate shaft 24, a proximal end

26 (not shown), and a distal portion 22. An electrode portion 30 and an insulator 32 are disposed proximate a distal end 18 of catheter 20.

As shown in Figure 13, elongate shaft 24 includes two lumens 36A, 36B. Catheter 20 includes a conductor 40 having a bent portion 42, a first leg 44, and a  
5 second leg 46. First leg 44 and second leg 46 are substantially disposed in lumens 36A and 36B respectively. Electrode 30 of catheter 20 is general formed from bent portion 42 of conductor 40. Insulator 32 defines two holes 48 which are adapted to allow legs 44, 46 of conductor 40 to pass through insulator 32.

Conductor 40 is fixed to insulator 32 by two adhesive bonds 902A, 902B  
10 which prevent bent portion 42 from moving before, or during a PMR procedure. Insulator 32 acting in conjunction with adhesive bonds 902A, 902B supports bent portion 42 of conductor 40, preventing it from being deformed during a PMR procedure.

Figure 14 is a plan view of a distal portion 22 of a catheter 20 in  
15 accordance with an alternate embodiment of the present invention. As in the previous embodiments catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. An electrode portion 30 and an insulator 32 are disposed proximate a distal end 18 of catheter 20.

As shown in Figure 14, elongate shaft 24 includes two lumens 36A, 36B.  
20 Catheter 20 includes a conductor 40 having a bent portion 42, a first leg 44, and a second leg 46. First leg 44 and second leg 46 are substantially disposed in lumens 36A and 36B respectively. Electrode 30 of catheter 20 is general formed from

bent portion 42 of conductor 40. Insulator 32 defines two holes 48 which are adapted to allow legs 44, 46 of conductor 40 to pass through insulator 32.

In the embodiment of Figure 14, lumens 36A, 36B of elongate shaft 24 are substantially filled with potting material 950. Potting material 950 serves to fix the location of conductor 30 relative to insulator 32 and elongate shaft 24. Potting material 950 may be comprised of a number of materials. Examples of suitable materials include silicone rubber and urethane. Catheter 20 and insulator 32 may include additional lumens (not shown in Figure 14) which allow a fluid to be conducted from proximal end 26 of catheter 20 to distal end 18 of catheter 20.

Figure 15 is a perspective view of a distal portion 22 of a catheter 20 in accordance with an alternate embodiment of the present invention. As in the previous embodiments catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. Elongate shaft 24 includes a distal end 910. An electrode 930 projects from distal end 910 of elongate shaft 24. In the embodiment of Figure 15, electrode 930 is comprised of a conductor 932 which is generally cylindrical in shape. During a PMR procedure in accordance with a presently preferred embodiment of the present invention, electrode 930 is energized with radio frequency energy causing it to create a wound. During wound formation, electrode 930 penetrates the tissue of the heart. Electrode 930 continues penetrating heart tissue until distal end 910 of elongate shaft 24 contacts the surface of the heart tissue.

Figure 16 is a perspective view of a distal portion 22 of a catheter 20 in accordance with an additional alternate embodiment of the present invention. As

in the previous embodiments catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. Elongate shaft 24 includes a distal end 910. An electrode 930 projects from distal end 910 of elongate shaft 24. In the embodiment of Figure 16, electrode 930 is comprised of two conductors 934 and 936. Conductors 934 and 936 are both generally cylindrical in shape. During a PMR procedure in accordance with a presently preferred embodiment of the present invention, electrode 930 is energized with radio frequency energy causing it to create a wound. During wound formation, electrode 930 penetrates the tissue of the heart. Electrode 930 continues penetrating heart tissue until distal end 910 of elongate shaft 24 contacts the surface of the heart tissue.

Figure 17 is a perspective view of a distal portion 22 of a catheter 20 in accordance with an additional alternate embodiment of the present invention. As in the previous embodiments catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. Elongate shaft 24 includes a distal end 910. An electrode 930 projects from distal end 910 of elongate shaft 24. In the embodiment of Figure 17, electrode 930 is comprised of two conductors 938 and 940. Conductors 938 and 940 are both generally arch shaped. During a PMR procedure in accordance with a presently preferred embodiment of the present invention, electrode 930 is energized with radio frequency energy causing it to create a wound. During wound formation, electrode 930 penetrates the tissue of the heart. Electrode 930 continues penetrating heart tissue until distal end 910 of elongate shaft 24 contacts the surface of the heart tissue.



Figure 18 is a perspective view of a distal portion 22 of a catheter 20 in accordance with an additional alternate embodiment of the present invention. As in the previous embodiments catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. Elongate shaft 24 includes a distal end 910. An electrode 930 projects from distal end 910 of elongate shaft 24. In the embodiment of Figure 18, electrode 930 is comprised of a straight portion 942 and a curved portion 944. During a PMR procedure in accordance with a presently preferred embodiment of the present invention, electrode 930 is energized with radio frequency energy causing it to create a wound. During wound formation, electrode 930 penetrates the tissue of the heart. Electrode 930 continues penetrating heart tissue until distal end 910 of elongate shaft 24 contacts the surface of the heart tissue.

Figure 19 is a perspective view of a distal portion 22 of a catheter 20 in accordance with an additional alternate embodiment of the present invention. As in the previous embodiments catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. Elongate shaft 24 includes a distal end 910. An electrode 930 projects from distal end 910 of elongate shaft 24. In the embodiment of Figure 19, electrode 930 is comprised of a straight portion 946 and a ring portion 948. During a PMR procedure in accordance with a presently preferred embodiment of the present invention, electrode 930 is energized with radio frequency energy causing it to create a wound. During wound formation, electrode 930 penetrates the tissue of the heart. Electrode 930 continues

penetrating heart tissue until distal end 910 of elongate shaft 24 contacts the surface of the heart tissue.

Figure 20 is a perspective view of a distal portion 22 of a catheter 20 in accordance with an additional alternate embodiment of the present invention. As  
5 in the previous embodiments catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. Elongate shaft 24 includes a distal end 910. An electrode 930 projects from distal end 910 of elongate shaft 24. In the embodiment of Figure 20, electrode 930 includes two straight portions 952 and 954 projecting from distal end 910 of elongate shaft 24. Electrode 930 also  
10 includes a hoop portion 956 having two ends 958. One end 958 of hoop 956 is joined to the distal end of straight portion 952. The other end 958 of hoop 956 is joined to the distal end of straight portion 954. During a PMR procedure in accordance with a presently preferred embodiment of the present invention, electrode 930 is energized with radio frequency energy causing it to create a  
15 wound. During wound formation, electrode 930 penetrates the tissue of the heart. Electrode 930 continues penetrating heart tissue until distal end 910 of elongate shaft 24 contacts the surface of the heart tissue.

Figure 21 is a perspective view of a distal portion 22 of a catheter 20 in accordance with an additional alternate embodiment of the present invention. As  
20 in the previous embodiments catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. Elongate shaft 24 includes a distal end 910. An electrode 930 projects from distal end 910 of elongate shaft 24. In the embodiment of Figure 21, electrode 930 includes two straight portions 962

and 964 projecting from distal end 910 of elongate shaft 24. Electrode 930 also includes an interconnecting portion 966 having two ends 968. One end 968 of interconnecting portion 966 is joined to the distal end of straight portion 962. The other end 968 of interconnecting portion 966 is joined to the distal end of straight portion 964. In the embodiment of Figure 21, interconnecting portion 966 is generally "U" shaped. During a PMR procedure in accordance with a presently preferred embodiment of the present invention, electrode 930 is energized with radio frequency energy causing it to create a wound. During wound formation, electrode 930 penetrates the tissue of the heart. Electrode 930 continues penetrating heart tissue until distal end 910 of elongate shaft 24 contacts the surface of the heart tissue.

Figure 22 is a perspective view of a distal portion 22 of a catheter 20 in accordance with an additional alternate embodiment of the present invention. As in the previous embodiments catheter 20 includes an elongate shaft 24, a proximal end 26 (not shown), and a distal portion 22. Elongate shaft 24 includes a distal end 910. An electrode 930 projects from distal end 910 of elongate shaft 24. In the embodiment of Figure 22, electrode 930 includes two straight portions 972 and 974 projecting from distal end 910 of elongate shaft 24. Electrode 930 also includes an interconnecting portion 976 having two ends 978. One end 978 of interconnecting portion 976 is joined to the distal end of straight portion 972. The other end 978 of interconnecting portion 976 is joined to the distal end of straight portion 974. In the embodiment of Figure 22, interconnecting portion 976 is generally "S" shaped. During a PMR procedure in accordance with a presently

preferred embodiment of the present invention, electrode 930 is energized with radio frequency energy causing it to create a wound. During wound formation, electrode 930 penetrates the tissue of the heart. Electrode 930 continues penetrating heart tissue until distal end 910 of elongate shaft 24 contacts the  
5 surface of the heart tissue.

Having thus described the preferred embodiments of the present invention, those of skill in the art will readily appreciate that yet other embodiments may be made and used within the scope of the claims hereto attached.

A PMR method in accordance with the present invention, may include the  
10 step of delivering a fluid to the wound site via catheter 102. Contact detecting means 706 may be used to verify that distal end 18 is proximate myocardial tissue before delivering the fluid. . This fluid may include saline, radiopaque contrast media, a therapeutic agent, a caustic agent, or any combination of these. Injecting a fluid including a radiopaque contrast media into the wound serves to create a  
15 radiopaque marker of a treatment site. Injecting a fluid, including a therapeutic agent, serves to promote angiogenesis. The formation of the wound may also be enhanced by collateral damage to the myocardium induced by directing pressurized fluid into the wound site. The impact of the pressurized fluid causes vessels, capillaries, and sinuses to rupture.

20 Numerous advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of parts without

exceeding the scope of the invention. The inventions's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A catheter assembly, comprising:

an elongate shaft having a proximal end, and a distal end;

a lumen defined by the elongate shaft and extending through at least a portion thereof;

a conductor including a bent portion, a first leg portion, and a second leg portion;

wherein the first and second leg portions are disposed in the lumen of the catheter; and

the bent portion of the conductor protruding from the distal end of the elongate shaft;

2. The catheter assembly of claim 1, further including a conductor lumen defined by the conductor.

3. The catheter assembly of claim 2, further including a hole defined by the conductor and in fluid communication with the conductor lumen.

4. The catheter assembly of claim 1, further including at least one retaining element disposed on the conductor proximate the distal end of the elongate shaft.

5. The catheter assembly of claim 4, wherein at least one retaining element is a crimp.
6. The catheter assembly of claim 4, wherein at least one retaining element is a weld bead.
7. The catheter assembly of claim 4, wherein at least one retaining element is a sleeve.
8. The catheter assembly of claim 4, wherein at least one retaining element is a kink.
9. The catheter assembly of claim 4, wherein at least one retaining element is a step.
10. The catheter assembly of claim 4, wherein at least one retaining element is a filler.
11. The catheter assembly of claim 4, wherein at least one retaining element is a localized area of greater width.
12. The catheter assembly of claim 1, wherein the conductor includes at least one tapered section.

13. The catheter assembly of claim 1, wherein the conductor is comprised of stainless steel.

14. The catheter assembly of claim 1, wherein the conductor is comprised of Nitinol.

15. The catheter assembly of claim 1, wherein the bent portion of the conductor is generally U shaped.

16. The catheter assembly of claim 1, further comprising a radio frequency generator connected to the conductor.

17. A catheter assembly, comprising:  
an elongate shaft having a proximal end, and a distal end;  
a lumen defined by the elongate shaft and extending through at least a portion thereof;  
an insulator fixedly attached to the elongate shaft proximate it's distal end;  
the insulator defining at least one hole;  
a conductor including a bent portion and at least one leg portion;  
the leg portion of the conductor passing through the hole of the insulator and being disposed in the lumen of the catheter; and



the bent portion of the conductor protruding from the distal end of the elongate shaft;

18. The catheter assembly of claim 17, further including a conductor lumen defined by the conductor.

19. The catheter assembly of claim 18, further including a hole defined by the conductor and in fluid communication with the conductor lumen.

20. The catheter assembly of claim 17, further including at least one retaining element disposed on the conductor proximate the insulator.

21. The catheter assembly of claim 20, wherein at least one retaining element is a crimp.

22. The catheter assembly of claim 20, wherein at least one retaining element is a weld bead.

23. The catheter assembly of claim 20, wherein at least one retaining element is a sleeve.

24. The catheter assembly of claim 20, wherein at least one retaining element is a kink.

25. The catheter assembly of claim 14, wherein at least one retaining element is a step.

26. The catheter assembly of claim 14, wherein at least one retaining element is a filler.

27. The catheter assembly of claim 14, wherein at least one retaining element is a localized area of greater width.

28. The catheter assembly of claim 17, wherein the conductor includes at least one tapered portion.

29. The catheter assembly of claim 17, wherein the conductor is comprised of stainless steel.

30. The catheter assembly of claim 17, wherein the conductor is comprised of Nitinol.

31. The catheter assembly of claim 17, further comprising a radio frequency generator connected to the conductor.

32. The catheter assembly of claim 17, wherein the bent portion of the conductor is generally U shaped.

33. A method of performing PMR, comprising the steps of:  
providing a catheter including an elongate shaft having a proximal end, a distal end;  
a conductor including a bent portion, a first leg portion, and a second leg portion;  
the conductor defining a conductor lumen and the bent portion of the conductor protruding from the distal end of the elongate shaft;  
positioning the distal end of the catheter proximate the endocardium of a patient's heart; and  
energizing the conductor with radio frequency energy.

34. The method of claim 33, wherein the elongate shaft includes landing zones proximate its distal end.

35. The method of claim 34, wherein the landing zones are adapted to halt the travel of the conductor into heart tissue.

36. The method of claim 33, further including the step of delivering a pressurized fluid through the distal end of the catheter.

37. The method of claim 36, wherein the fluid includes a therapeutic agent.
38. The method of claim 36, wherein the fluid includes a contrast media.
39. The method of claim 36, wherein the fluid includes saline.
40. The method of claim 37, wherein the therapeutic agent is a growth factor.

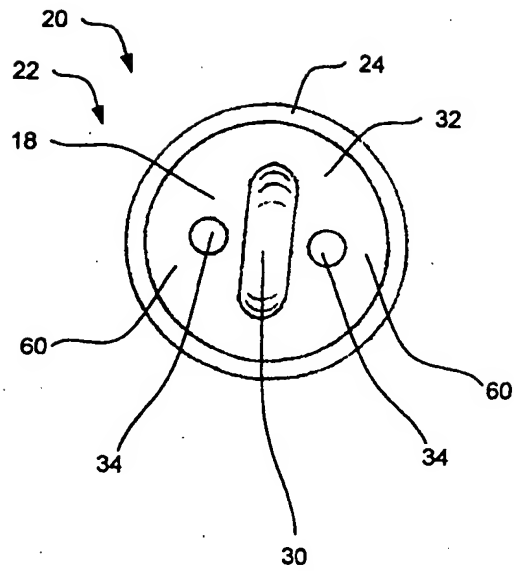


FIG. 1

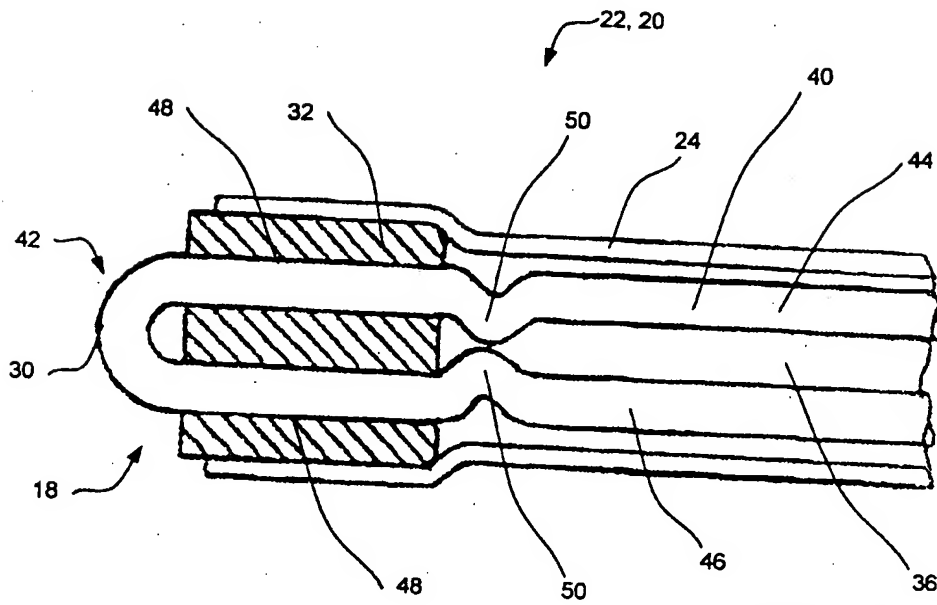
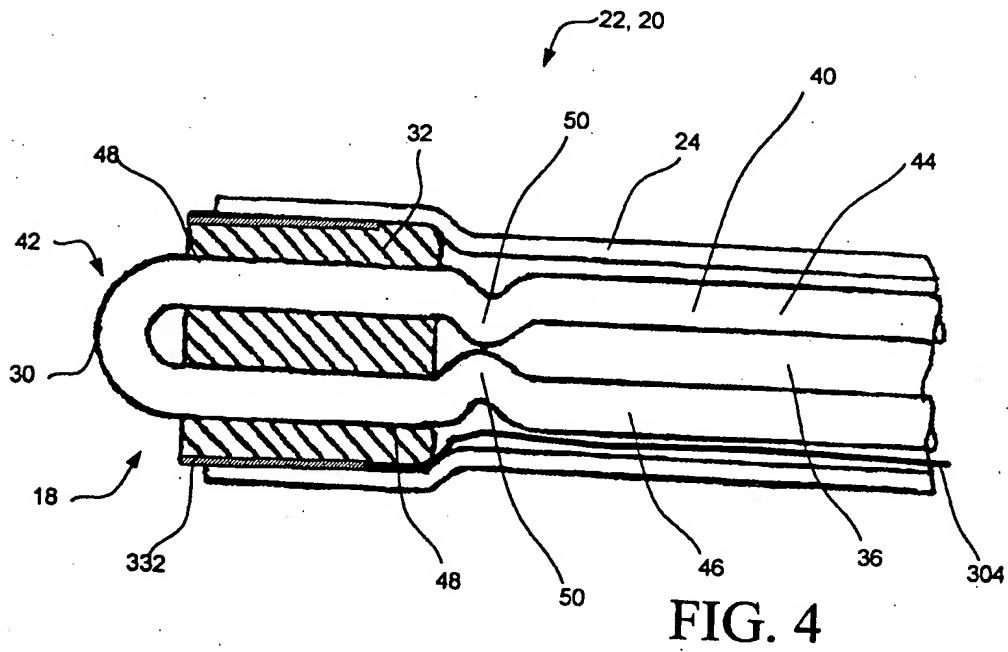
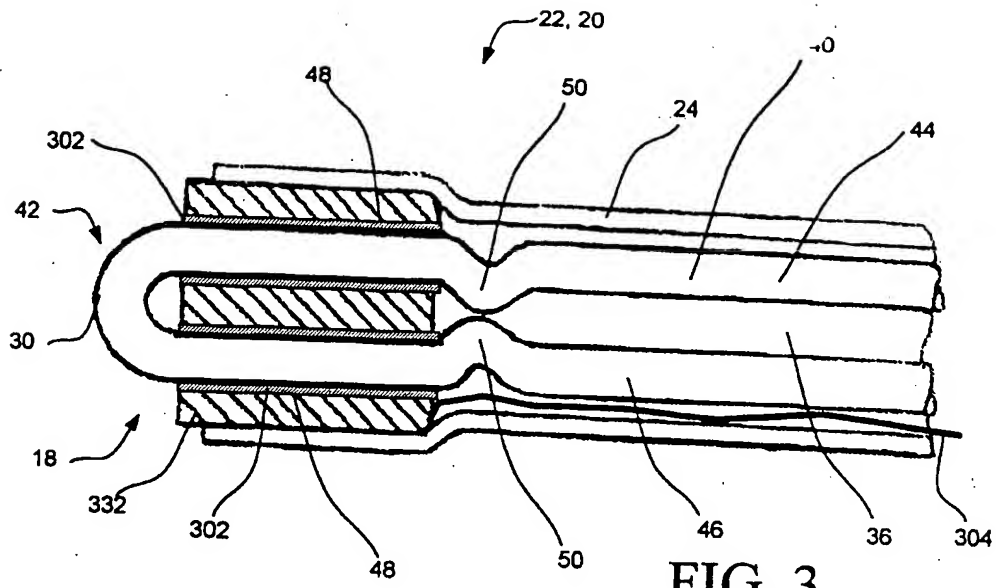
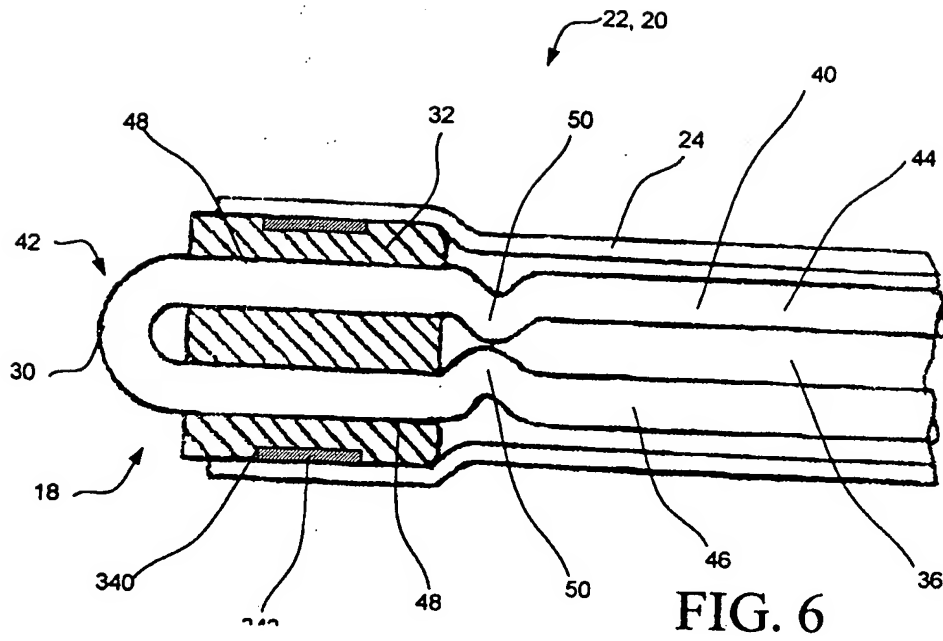
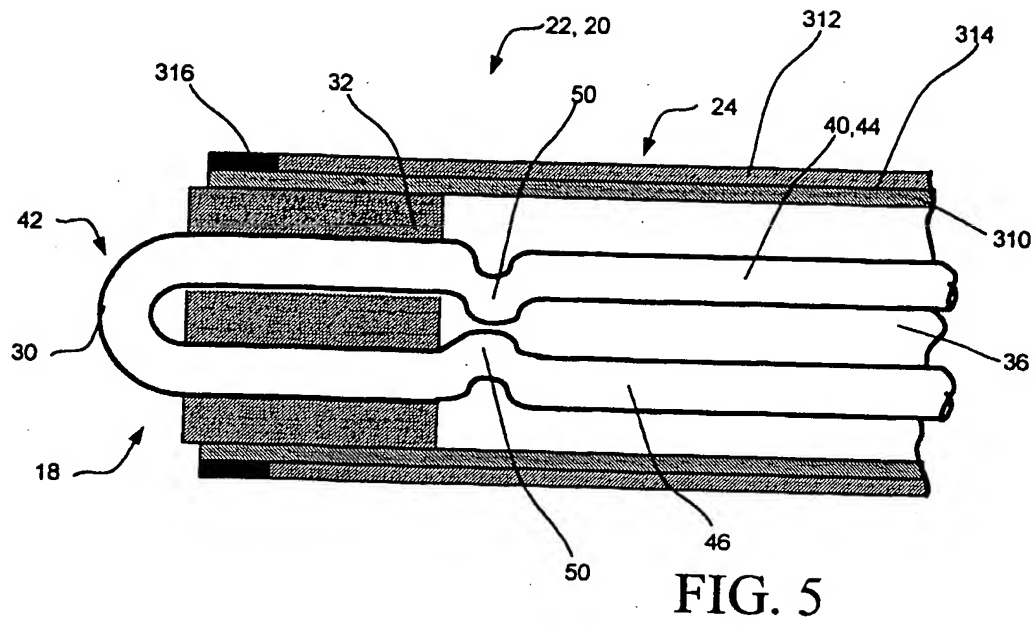


FIG. 2





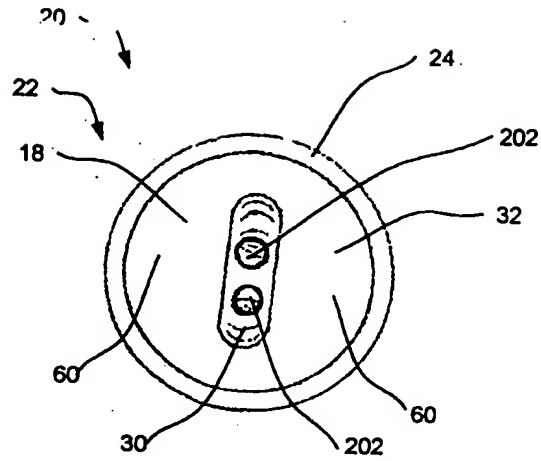


FIG. 7

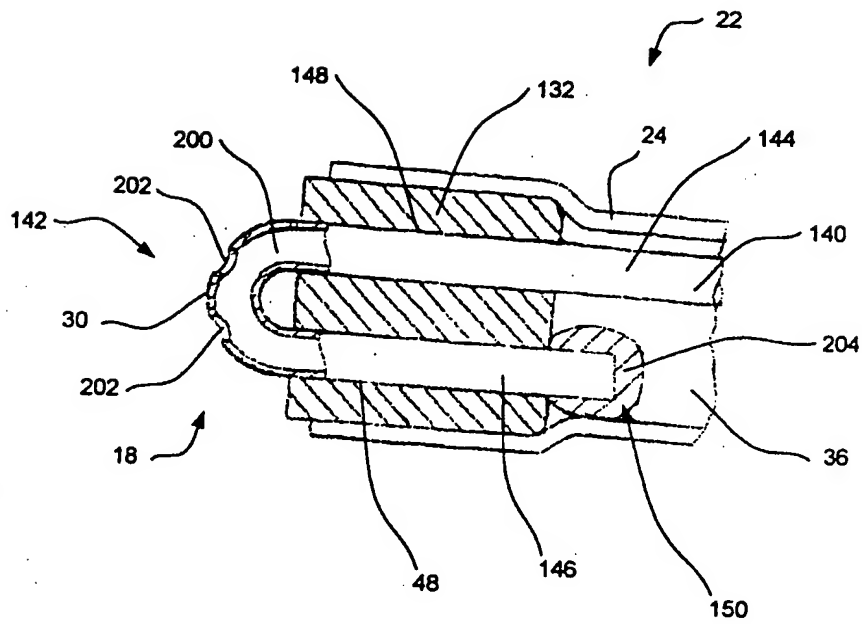


FIG. 8



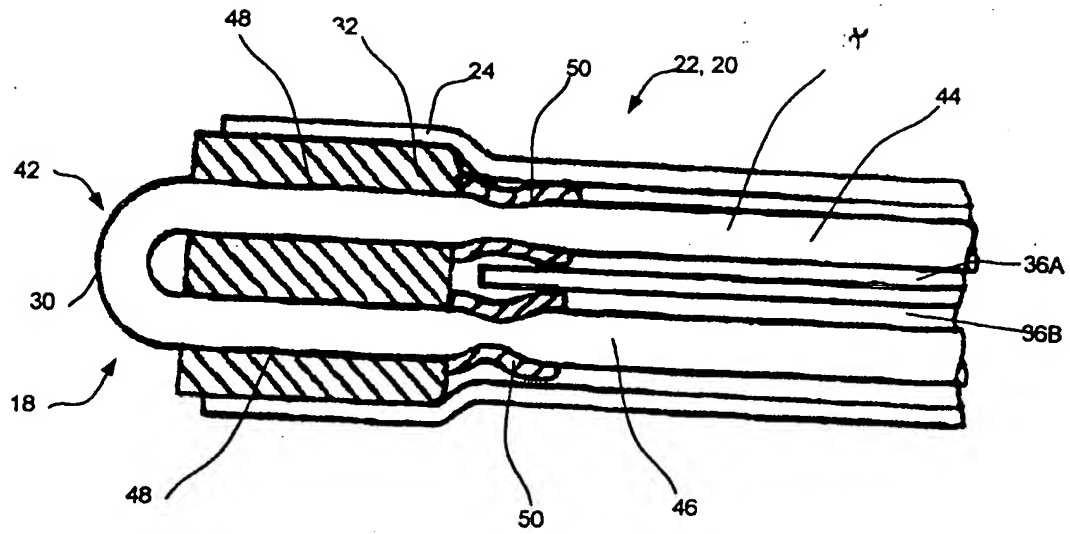


FIG. 9

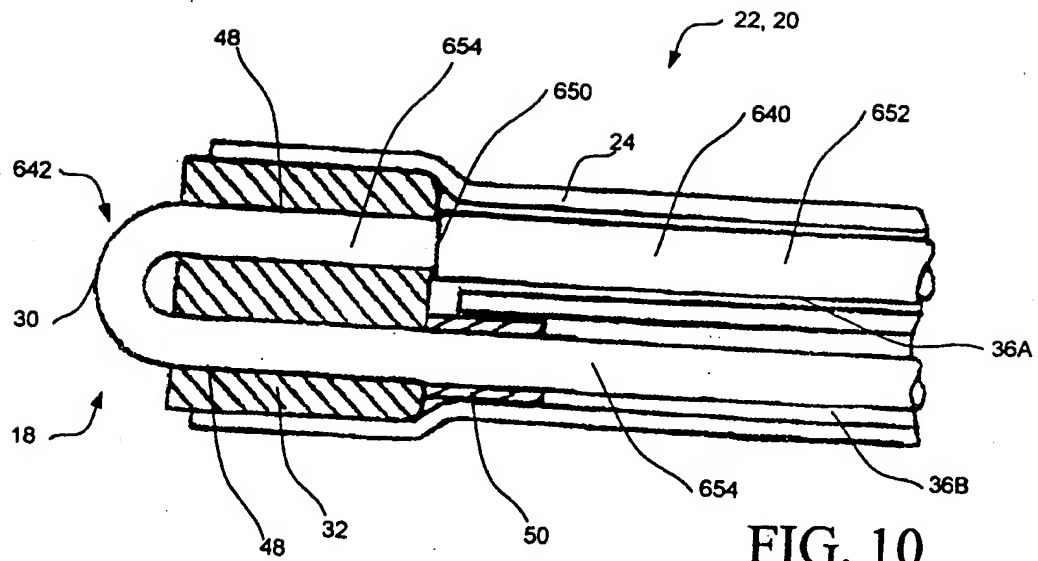


FIG. 10

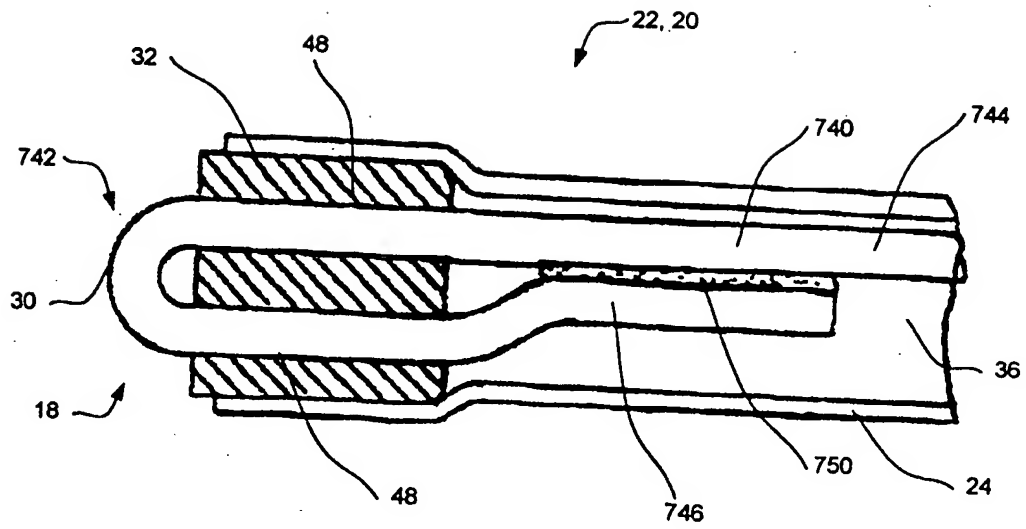


FIG. 11

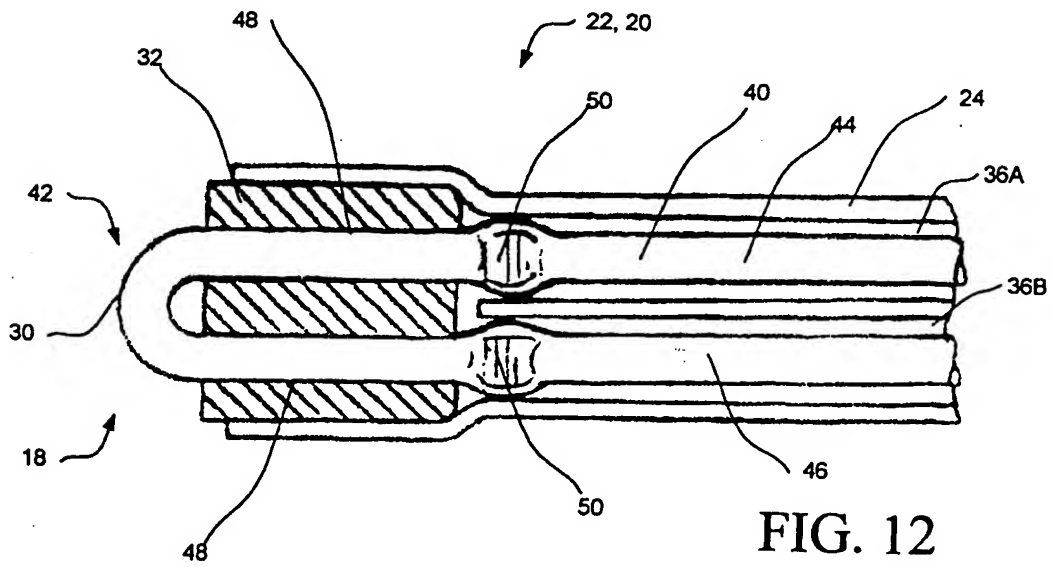


FIG. 12

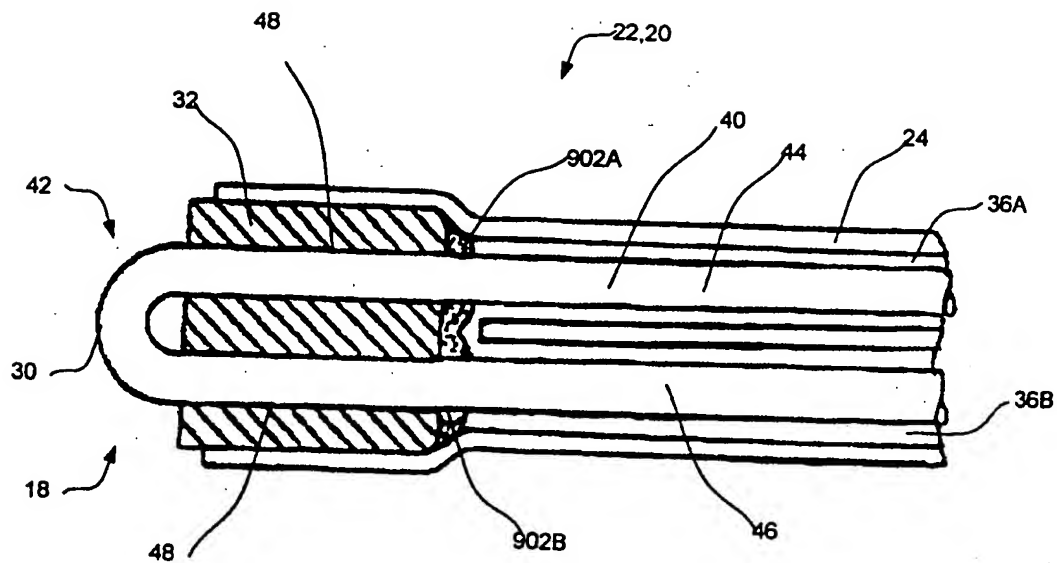


FIG. 13

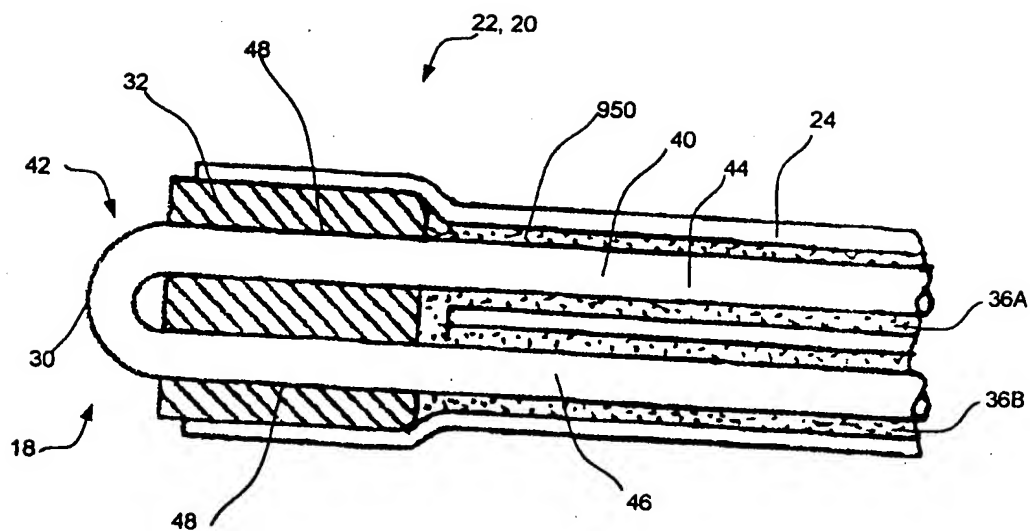


FIG. 14

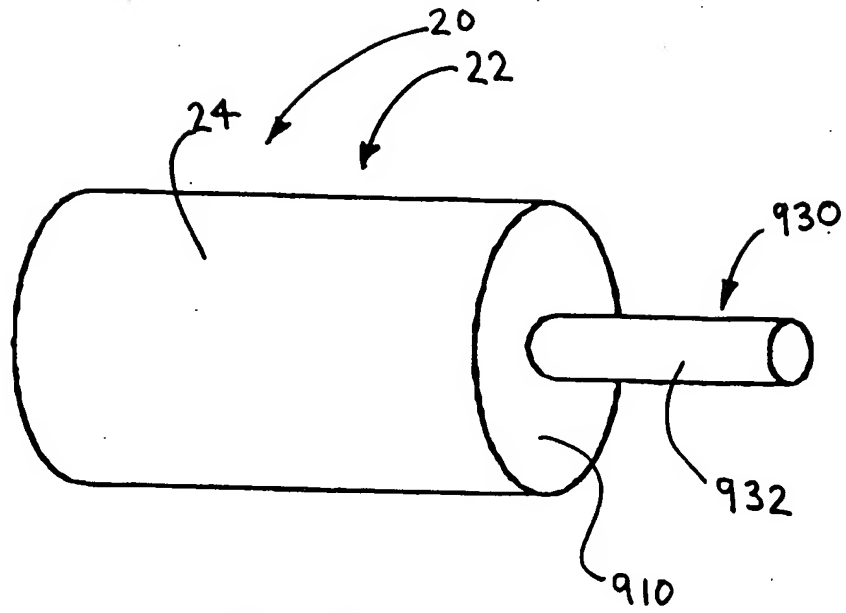


FIG. 15

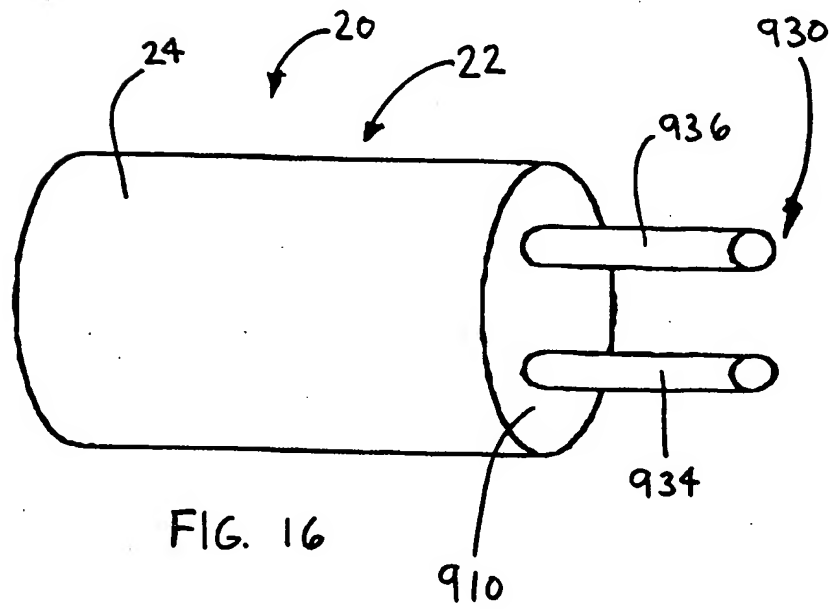
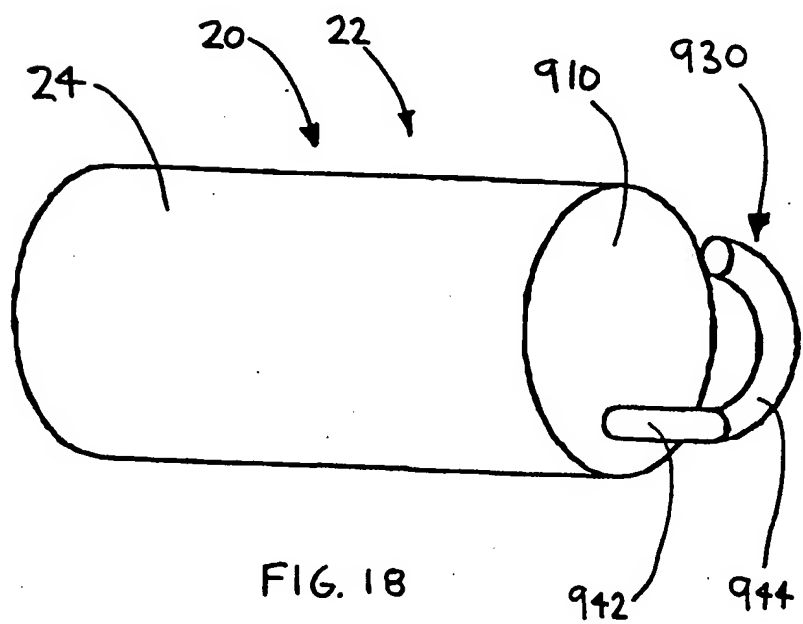
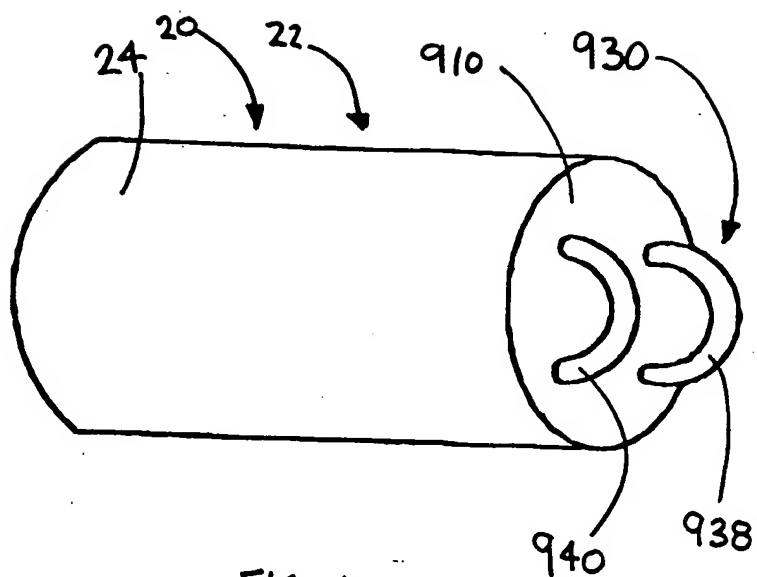
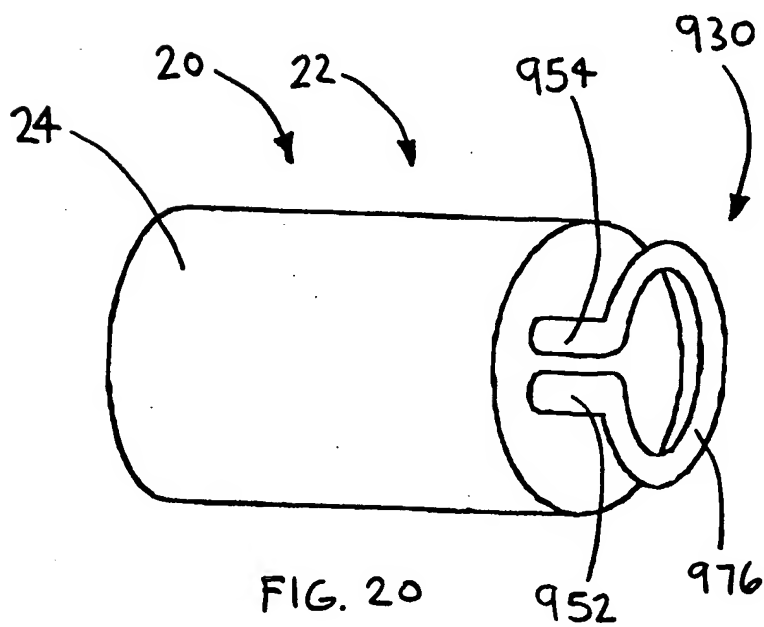
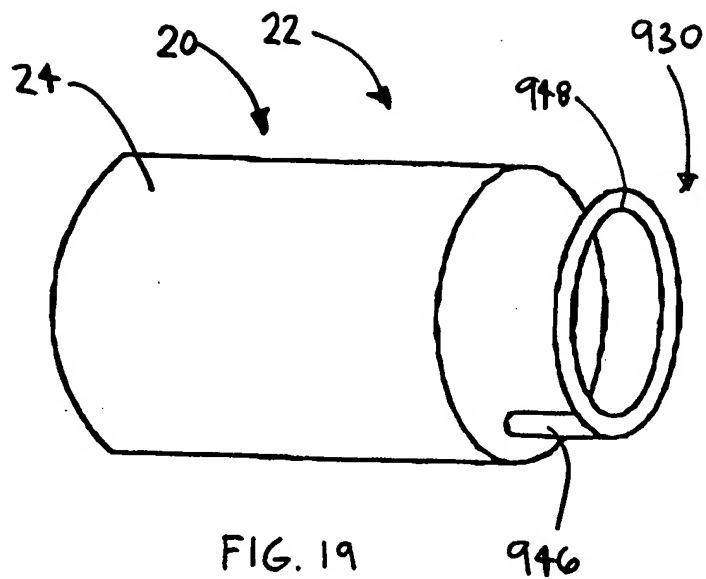
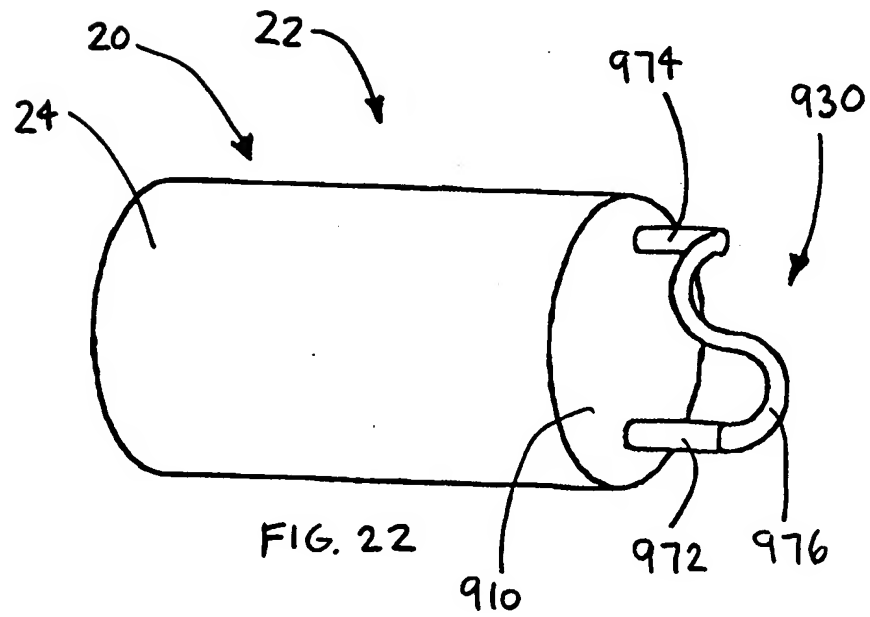
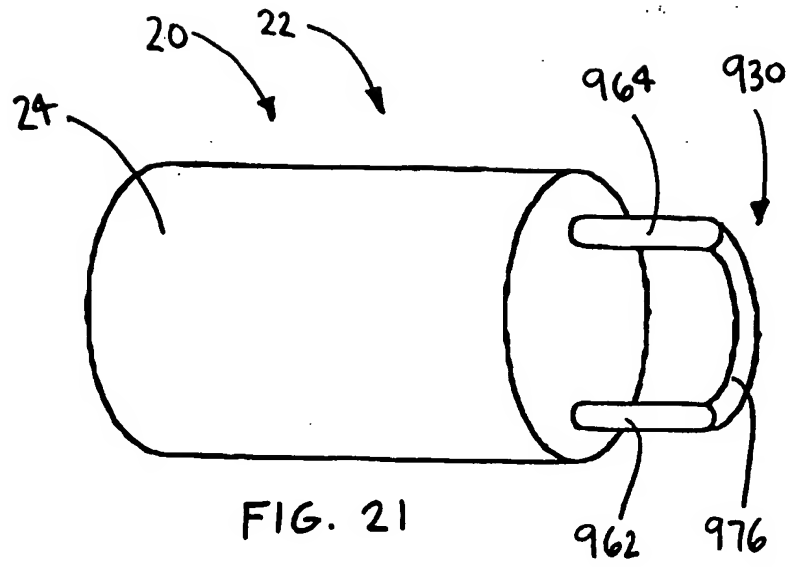


FIG. 16







# INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 00/04977

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B18/14

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 860 951 A (EGGERS PHILIP E ET AL) 19 January 1999 (1999-01-19) figures 5,6,10A,11 ----	1,17
A	EP 0 868 923 A (ECLIPSE SURGICAL TECH) 7 October 1998 (1998-10-07) see description fig 14 ----	1
A	US 5 871 469 A (EGGERS PHILIP E ET AL) 16 February 1999 (1999-02-16) column 21, line 32-37 -----	1,17

☐ Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

### \* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

12 July 2000

Date of mailing of the international search report

18/07/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Papone, F



# INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/US 00/04977

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5860951 A	19-01-1999	US 5683366 A	04-11-1997
		US 5697281 A	16-12-1997
		US 5366443 A	22-11-1994
		AU 709928 B	09-09-1999
		AU 1057197 A	11-06-1997
		CA 2237795 A	29-05-1997
		EP 0865256 A	23-09-1998
		JP 3033848 B	17-04-2000
		JP 11502144 T	23-02-1999
		NZ 323589 A	29-07-1999
		US 6032674 A	07-03-2000
		WO 9718768 A	29-05-1997
		US 5873855 A	23-02-1999
		AU 706294 B	10-06-1999
		AU 6026696 A	30-12-1996
		CA 2221330 A	19-12-1996
		EP 0837647 A	29-04-1998
		JP 2912023 B	28-06-1999
		JP 10510745 T	20-10-1998
		US 6063079 A	16-05-2000
		US 6053172 A	25-04-2000
		WO 9639914 A	19-12-1996
		US 6066134 A	23-05-2000
		US 5697882 A	16-12-1997
		US 6024733 A	15-02-2000
		US 5810764 A	22-09-1998
		US 5843019 A	01-12-1998
		US 5902272 A	11-05-1999
		US 5697536 A	16-12-1997
		US 5871469 A	16-02-1999
		AU 711197 B	07-10-1999
		AU 2472497 A	14-08-1997
		AU 676329 B	06-03-1997
		AU 6829694 A	12-12-1994
		CA 2162395 A	24-11-1994
		EP 0697841 A	28-02-1996
		JP 2931102 B	09-08-1999
		JP 9501328 T	10-02-1997
		NZ 266678 A	19-12-1997
		WO 9426228 A	24-11-1994
		US 5681282 A	28-10-1997
		US 5888198 A	30-03-1999
		US 5891095 A	06-04-1999
		AT 173903 T	15-12-1998
		AU 3335793 A	03-08-1993
		CA 2129745 A	08-07-1993
		DE 69227783 D	14-01-1999
		DE 69227783 T	20-05-1999
		EP 0624076 A	17-11-1994
		EP 0882430 A	09-12-1998
EP 0868923 A	07-10-1998	US 5876373 A	02-03-1999
		AU 5845398 A	08-10-1998
		CA 2233898 A	04-10-1998
		JP 10295822 A	10-11-1998
US 5871469 A	16-02-1999	US 5697882 A	16-12-1997
		US 5697281 A	16-12-1997

# INTERNATIONAL SEARCH REPORT

information on patent family members

Inter national Application No

PCT/US 00/04977

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5871469 A		US 5366443 A	22-11-1994
		US 6066134 A	23-05-2000
		AU 702687 B	04-03-1999
		AU 1054597 A	11-06-1997
		CA 2237947 A	29-05-1997
		EP 0886493 A	30-12-1998
		JP 2000060868 A	29-02-2000
		JP 11501555 T	09-02-1999
		WO 9718765 A	29-05-1997
		US 5843019 A	01-12-1998
		AU 706294 B	10-06-1999
		AU 6026696 A	30-12-1996
		CA 2221330 A	19-12-1996
		EP 0837647 A	29-04-1998
		JP 2912023 B	28-06-1999
		JP 10510745 T	20-10-1998
		US 6032674 A	07-03-2000
		US 6063079 A	16-05-2000
		US 6053172 A	25-04-2000
		WO 9639914 A	19-12-1996
		US 5683366 A	04-11-1997
		US 6024733 A	15-02-2000
		US 5810764 A	22-09-1998
		US 5902272 A	11-05-1999
		US 5697536 A	16-12-1997
		US 5860951 A	19-01-1999
		US 5873855 A	23-02-1999
		AU 711197 B	07-10-1999
		AU 2472497 A	14-08-1997
		AU 676329 B	06-03-1997
		AU 6829694 A	12-12-1994
		CA 2162395 A	24-11-1994
		EP 0697841 A	28-02-1996
		JP 2931102 B	09-08-1999
		JP 9501328 T	10-02-1997
		NZ 266678 A	19-12-1997
		WO 9426228 A	24-11-1994
		US 5681282 A	28-10-1997
		US 5888198 A	30-03-1999
		US 5891095 A	06-04-1999
		AT 173903 T	15-12-1998
		AU 3335793 A	03-08-1993
		CA 2129745 A	08-07-1993
		DE 69227783 D	14-01-1999
		DE 69227783 T	20-05-1999
		EP 0624076 A	17-11-1994
		EP 0882430 A	09-12-1998
		NZ 246503 A	26-07-1996